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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,657	04/16/2007	Hans-Joachim Runge	930008-2210 (BOE0006US.N	2806

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EXAMINER	
KLINKEL, KORTNEY L	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,657	RUNGE ET AL.	
	Examiner	Art Unit	
	Kortney Klinkel	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *07 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,27-31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) *5-25 and 27-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4* is/are rejected.

7)☒ Claim(s) *5-25 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

Claims 1-25 and 27-31 and 33-36 are pending in the instant Office action.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-26 and 36 in the reply filed on July 7, 2008 is acknowledged. The traversal is on the ground(s) that the special technical feature of the instant invention in unmilled flutamide and that the references cited by the Examiner do not teach this feature. This is not found persuasive because Reference US 4474813 teaches a tablet containing unmilled flutamide. Please see column 2, lines 25-40 in which the recited ingredients are formed into a tablet using the wet granulation method. No milling is involved. Furthermore references US 3995060 at column 17, lines 14-16 teaches unmilled flutamide along with a surfactant which are blended together. Applicants further state that the present invention relates to a process that enables unmilled flutamide to have bioequivalence and that the bioequivalence is achieved by *intensively mixing* the unmilled flutamide with a surface-active substance. It is unclear how intensively mixing is different from milling. Therefore, even if the two references relied upon by the Examiner did not teach unmilled flutamide, Applicants arguments would still be unpersuasive.

Applicants further argue that no additional burden would be placed upon the Examiner in searching together the subject matter of Group I and Group II. However, the establishment of burden on the Office applies to US cases only. The instant

application is a national stage entry of an international application under 35 U.S.C. 371. As a result, lack of unity practice is observed for restriction purposes.

Acknowledgement is also made of Applicant's election of sodium dodecylsulphate as the surface-active substance, magnesium stearate as the flow regulator and microcrystalline cellulose as the excipients, with traverse. Applicant's arguments that each of the surface-active substances, flow regulators, excipients, and pharmaceutically active ingredients are functioning in the same manner in the instant formulation has been found persuasive and therefore the species election requirement has been withdrawn.

The restriction requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

Acknowledgement is made of applicant's submitting an information disclosure statement on September 21, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Applicants are also reminded that the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Foreign Priority

Acknowledgement is made of applicant's foreign priority claim to German patent application serial number 10 2004 014 272.6 filed March 22, 2004. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks Eulexin® (page 3), Tweens® (page 8), Collette Vactron®, Lodige®, Diosna®, and Bohle-Vagumat® (page 10), have been noted in this application. Trademarks should be capitalized wherever they appear or include the appropriated trademark symbol ***and*** be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 5-25 and 36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, in the case of claim 5 and 36 and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). *Accordingly, the claims 5-25 have not been further treated on the merits.* Therefore, claims 1-4 are under examination in the instant Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Neri et al. (US 4474813).

Neri '813 teaches a pharmaceutical formulation comprising flutamide, which is necessarily either crystalline and/or amorphous, sodium lauryl sulfate (a surface-active substance), magnesium stearate (a flow regulator) *inter alia*, which are mixed using a wet granulation method. Wet granulation is not milling, therefore the flutamide is unmilled (column 2 lines 25-39). The mixture is formed into tablets (column 2, line 25), and a filling for capsules (column 2, line 54) as well as a suppository (column 3, lines 16-17).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Neri et al. (US 3995060).

Neri '060 teaches pharmaceutical formulations comprising flutamide (4-nitro-3-trifluoromethylisobutyranilide), which is necessarily either crystalline and/or amorphous, sodium lauryl sulfate (a surface-active substance) which are mixed in a bowl (column 17, lines 14-16). The mixture is not milled until subsequent steps (see column 17, lines 17-20). Furthermore, step 3 (lines 21-23) admits that the first milling contains unmilled fractions of flutamide and sodium lauryl sulfate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neri (US 3995060).

Neri '060 teaches a pharmaceutical formulation comprising unmilled flutamide and sodium lauryl sulfate (column 17, lines 14-16). Neri further teaches that flutamide can be formulated into tablets, capsules, and suppositories and that in the tablet form they are compounded with an inert carrier or binder such as gums, starches and sugars (column 14, lines 40-61). Neri '060 further teaches tablet formulations (column 15, lines 20-33), capsule formulations (column 15, lines 47-54) and parenteral suspension formulations (column 16, top). It is not specified what form (milled or unmilled) the flutamide in these formulations is in. However, the capsule formation (column 16, bottom) specifies that the flutamide is milled. One or ordinary skill in the art could infer, then that the tablet and capsule formulations of column 15 comprise unmilled flutamide since it is not specified that the flutamide is milled. Even if this is not the case, because Neri '060 teaches both milled and unmilled flutamide for use in pharmaceutical

formulations, with a surface active agent it would have been obvious to one of ordinary skill in the art at the time of the instant invention to form tablets, capsules, dragee, effervescent tablets, suppositories or granulates with unmilled flutamide and a surface active agent with a reasonable expectation of success.

Conclusion

Claims 1-4 are rejected. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, Ph.D. whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615